

The effect of miacalcic nasal spray in the management of spinal stenosis

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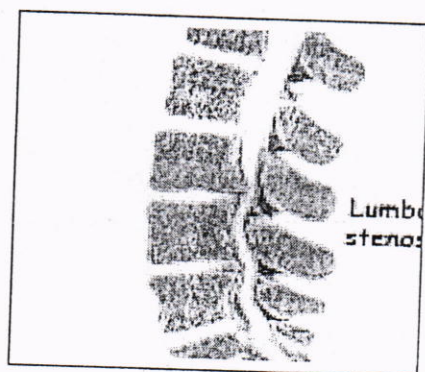
Abstract

The study was conducted in Tikrit Teaching Hospital during the period between April 2006 to April 2008; from the out patient department 39 patients with spinal stenosis were included in the study (6 males and 33 females). The age range from 37 – 82 years. The patients were divided into two groups both treated conservatively, but one of them calcitonin nasal spray was used in the treatment schedule. The aim of the study was to recognize the efficacy of calcitonin nasal spray in the management of spinal stenosis. The study showed a high rate of incomppliance to calcitonin mainly to economic factor. The study revealed that 84% of patients treated with calcitonin nasal spray had a good pain relief. While the response for claudication distance was approximately the same for both patients' groups. No patient develops any side effect. The study concludes that calcitonin nasal spray is effective in alleviating symptoms of patients with spinal stenosis.

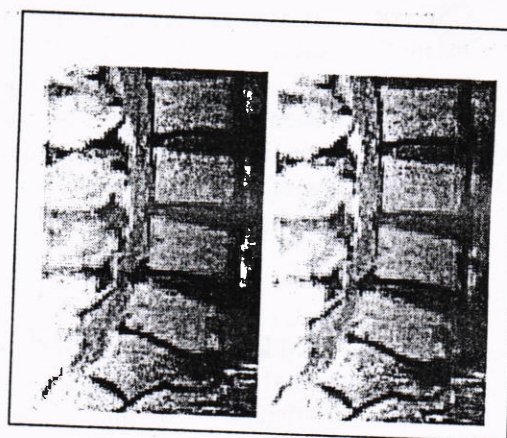
Introduction

Lumbar spinal stenosis (LSS) is a common and often disabling disorder that generally occurs in the sixth or seventh decade of life [1], although it can uncommonly occur in younger individuals [2]. The incidence of this condition has been reported to be 8–11% [3], with a slight preponderance in women [1]. LSS can lead to low back and leg pain, most typically via encroachment on the central canal, lateral recess, or lateral canal (fig. 1).

The source of the encroachment is typically vertebral body osteophytes, hypertrophy of the ligamentum flavum or zygapophyseal joint, or a combination of these [1]. The posterior longitudinal ligament may be involved in some individuals [4]. The development of these degenerative changes is often accompanied by restriction of segmental mobility [1].



MRI is the investigation of choice for the diagnosis of spinal stenosis in which the MRI myelography can be described as being beaded in its appearance. (fig. 2)



One of the hallmarks of LSS is neurogenic claudication, in which the patient develops low back and/or leg pain after a period of walking that progressively worsens as walking is continued, with improvement or resolution when walking ceases and the patient sits or flexes the lumbar spine [5].

LSS is one of the most common reasons for spine surgery in older people [6], although little is known about the efficacy of surgical management of patients with LSS, particularly compared to non-surgical management [7]. It is generally felt that most

patients with LSS should be managed non-surgically before considering surgical intervention [8], but little is also known about what non-surgical approaches are most efficacious.

Experimental evidence has suggested that chronic compression of the nerve root in LSS causes compromise of blood flow leading to congestion, ischemia, and intraneural edema [9]. This then leads to the development of periradicular fibrosis [10]. Increased pain with walking that is relieved with lumbar flexion (neurogenic claudication) is one of the hallmarks for LSS. Neurogenic claudication likely arises from increased metabolic demands of the nerve root in the presence of vascular compromise [11] and traction on the adhered nerve root when lower extremity movement occurs during walking [12].

This may explain why the SLR (straight leg raising test) is often negative in pts with LSS [8], but is typically positive in patients with herniated disc. With LSS, compression, vascular compromise and perineural fibrosis dominate the pathophysiological picture, thus maneuvers that increase CSF pressure, i.e., extension [13], or increase metabolic demands of the nerve root and movement of the fibrotic nerve root, as with walking, exacerbate the pain.

Several small clinical trials reported beneficial effects of calcitonin in patients with spinal stenosis. Improvement in both pain and walking tolerance has been described.

The beneficial effects were usually apparent within 4 to 6 weeks. (14-17) However; a recently completed double blind, randomized, placebo-controlled trial was unable to demonstrate clinical effectiveness of calcitonin administered by nasal spray in persons with spinal stenosis. Though calcitonin's mechanism of action is unknown, some speculate that it acts nonspecifically by raising the level of endogenous opioids (beta endorphins) (18, 19). Alternatively, others have suggested that calcitonin may improve symptoms by enhancing circulation to an ischemic cauda equina (15).

Flushing or nausea, the two main side effects, are seen in fewer than 5% of patients treated with calcitonin (14-16)

The aim of the study is to recognize the efficacy of calcitonin nasal spray in the management of spinal stenosis.

Patients and Methods

The study was conducted in Tikrit Teaching Hospital during the period between April 2006 to April 2008, from the out patient department 39 patients with spinal stenosis were included in the study (6 males and 33 females). The age range from 37 – 82 years (mean = 57.8 years).

All of the patients were treated conservatively, a group of 13 patients with calcitonin nasal spray (13 patients) after meticulous history taken to exclude allergy to fish, and a group without (8 patients). There were 18 patients, who supposed to be treated with calcitonin, were non compliant and refuse the calcitonin for many causes, thus they were treated without calcitonin and added to the group of patients treated without calcitonin. Patients on nasal spray calcitonin were continued on treatment for at least 4 weeks. Each patient of both groups was followed for 2-3 months. After this period the patients were reassessed and asked about the symptomatic improvement.

Statistical analysis was done to fine out the significance of the results according to the P value.

Results

The study reveals that most of the patients with spinal stenosis were female, and most of them were from 45 – 60 years old (table 1)

The compliance of the patient to calcitonin were poor 46% of the whole sample refuse calcitonin nasal spray for mainly 2 causes, either not available or expensive (Figure 3) Regarding pain relieving effect of calcitonin in spinal stenosis, the present study show 84.6% of patients treated with calcitonin nasal spray describe the pain relief as good compared to those treated without calcitonin, were only 23% consider the pain relief as good. This result is clearly shown in table 2.

This study clarified that the effect on claudication distance was comparable for both groups (See figure 4). Four patients treated with calcitonin nasal spray 23.1% assess the improvement in claudication distance as good, 61.5% as fair, and 15.4 %.

Compared to those patients treated without calcitonin 19.2%, 61.5%, and 19.2% respectively.

Overall patients assessment showing better results with calcitonin in comparison to those without (see table 3). 61.5 % of patients on calcitonin assess the improvement in their condition as good. In contrast, only 23.1% of patients treated without calcitonin assess their outcome as good.

None of our patients developed any of the known side effects to nasal spray calcitonin.

Discussion

The present study show significant results of higher incidence of spinal stenosis in female patients. Arbit agrees with this ⁽¹⁾. The study show poor patients compliance to calcitonin nasal spray. And the result was statistically significant. Previous studies porter et al ⁽¹⁴⁻¹⁶⁾ disagrees, but the in compliance in our study most probably due to pure local factors, insecurity and poverty.

This study show remarkable pain relief in patients on nasal calcitonin. This might be hypothetically due to decrease venous congestion. The results were statistically significant (P value < 0.05). This is agreed by Overgaard ⁽²⁰⁾ and Eskola ⁽¹⁴⁾. While Tafazal ⁽²¹⁾ and Podichetty ⁽²²⁾ disagreed with this finding.

The present finding of difference in the claudication distance improvement was statistically not significant. This might be due to short period of patients follow up. This finding was agreed with by Tafazal ⁽²¹⁾. While Eskola ⁽¹⁴⁾ disagrees and described a significant improvement of claudication distance with clacitonin.

The overall assessment was significantly better for the patients receiving calcitonin nasal spray (table 3). Tafazal (21) and Podichetty (22) disagree with this finding and deny any therapeutic effect of calcitonin in cases of spinal stenosis.

The present study failed to notice any side effect to nasal spray calcitonin. While Eskola (21) notices a rarely occurring very transient side effect like erythema and

nausea, as part of allergic response to Salmon fish from which calcitonin was taken. We tried to prevent this by thoroughly asking our patients for allergy to any type of fish.

The study concludes a valuable satisfaction by the patients with spinal stenosis in response to nasal spray calcitonin.

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Table (1): the age / sex distribution of the cases

Age	Male	Female
< 45	1	3
45 - 60	1	21
60 >	4	9
Total	6	33

Table (2): the pain relief in response to calcitonin compared to other modalities of treatment.

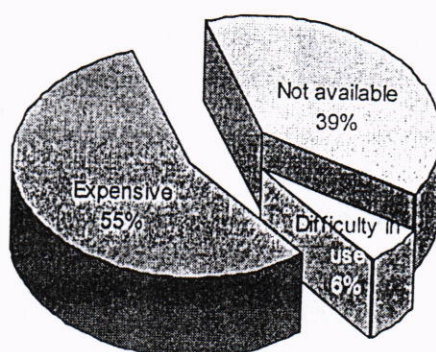
Treatment modality	Pain relief							
	Good		Fair		Poor		Total	
	No.	%	No.	%	No.	%	No.	%
With calcitonin	11	84.6	2	15.3	0	0	13	100
Without calcitonin	6	23	17	65.4	3	11.5	26	100

Table (3): overall patients assessment to their final outcome.

Treatment modality	Overall patient's assessment							
	Good		Fair		Poor		Total	
	No.	%	No.	%	No.	%	No.	%
With calcitonin	8	61.5	5	38.5	0	0	13	100
Without calcitonin	6	23.1	15	57.7	5	19.2	26	100

Causes of incomppliance

Fig 3



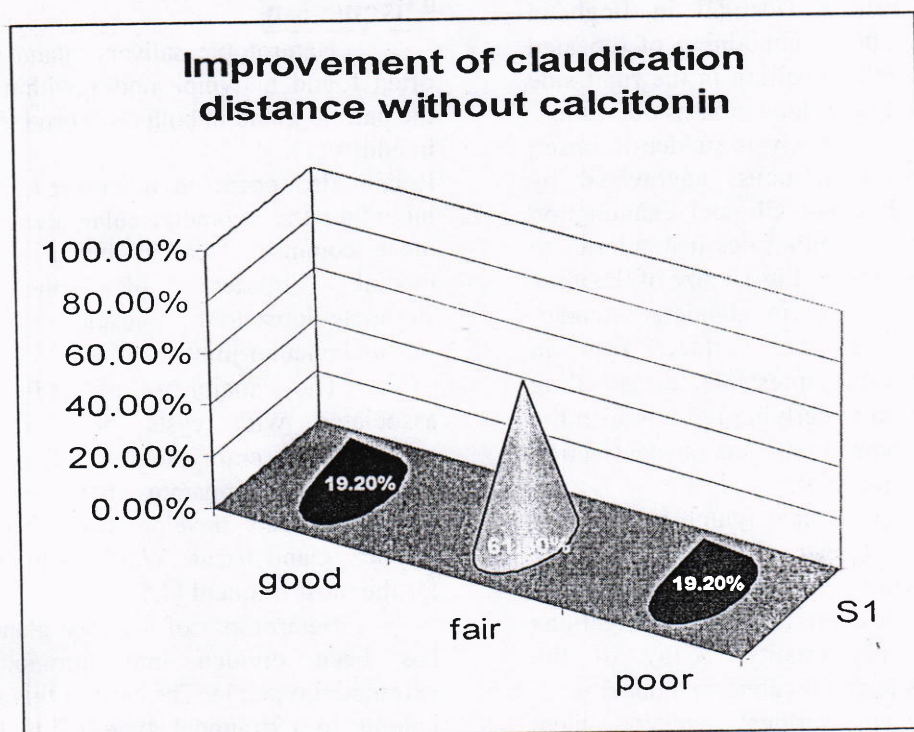
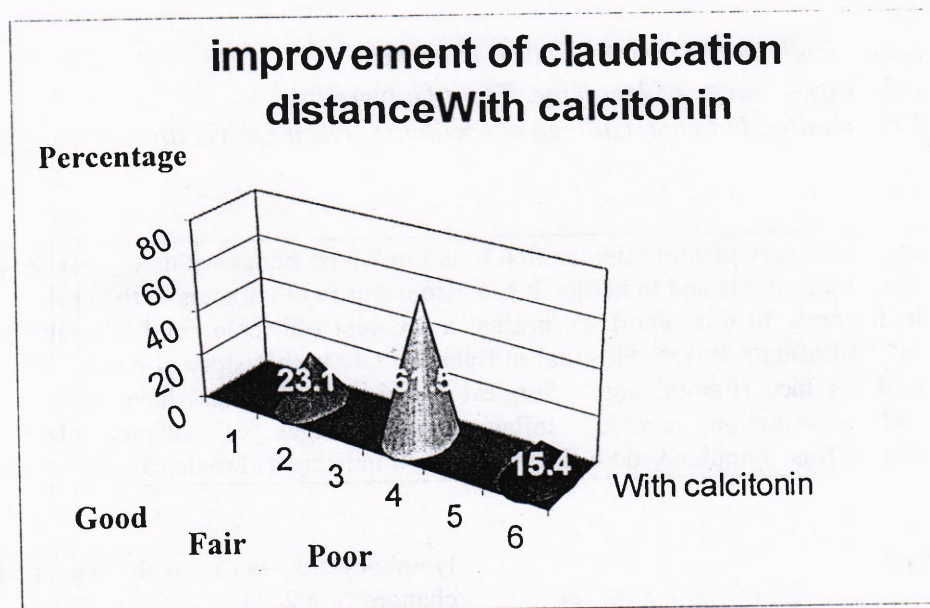


Figure (4): the improvement in claudication distance.